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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Beckman et al. : Paper No:

Serial No. 10/815,004 : Group Art Unit: 3736

Filed: March 31, 2004 : Examiner: Rene T. Towa

For: MARKER DEVICE AND METHOD OF DEPLOYING A CAVITY MARKER

USING BIOPSY DEVICE

Confirmation No. 1279

RESPONSE

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In the subject Office Action dated October 20, 2006, claims 1-6, 8-9 and 11-24 were examined. The arguments presented herein do not pose new issues and are for the purpose of advancing the case toward allowance and issue and are thus admissible after final under 37 CFR § 1.116.

In the subject Office action, claims 1, 3, 8-9, 11-15 and 17-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view Burbank et al. (US Patent No. 6,662,041). Claim 16 was rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Burbank et al. ('041) further in view of Lamoureux et al. (US Patent No. 6,554,760). Claims 2 and 6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Burbank et al. ('041) further in view Burbank et al. (US Patent No. 6,161,034). Claims 4-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Burbank et al. ('041) further in view Zarins et al. (US Patent No. 6,605,047). Claims 20-21 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch

('177) in view of Burbank et al. ('041) further in view of Miller et al. (US Patent No. 6,638,235). Claims 22-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Burbank et al. ('041) further in view of Miller et al. ('235) even further in view of Zarins et al. ('047).

Turning to independent claim 1, the claim recites in part distally advancing a cutter to drive a pusher and thus a marker to cause deployment of the marker through the distal opening of a cutter lumen at the biopsy surgical site.

In rejecting claim 1, the Examiner relied upon the teaching of Barsch ('177) to disclose the limitation of a pusher driven by the cutter as follows: "distally advancing the cutter 52 to drive the pusher 52 and thus the marker 42 to cause deployment at the biopsy surgical site (see fig. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42)."

Applicants traverse the rejection as failing to make a prima facie case for obviousness. The Examiner has failed to point out an element of the claim of a separate pusher that is driven by the cutter. This omission is pointed out later in the Office action:

In regards to claims 1 and 12, Barsch discloses a system, as described above, teaches all the limitations of the claims except Barsch does not teach a plunger that is separable into a pusher and a cutter. However, since Barsch discloses a plunger 52 (see fig. 4C), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a pusher and a cutter since such a modification would amount to a design choice, which serves the same purpose of moving the marker for deployment (see fig. 6). Moreover, Applicant has not disclosed that having a plunger that is separable into a pusher and a cutter provides an advantage, is used for a particular purpose, or solves a stated problem. Even further yet, it has previously been held that making separable is not patentable-See *In re Dulberg, 289 F. 2d 522, 523, 129 USPQ 348, 349 (CCPA 1961)*.

Applicants assert that separating the plunger of Barsch into a cutter and a pusher is not a design choice. The distal end of the plunger of Barsch is taught as having a shape specific to urging a marker out of the side aperture. Barsch itself teaches a conventional core biopsy device 10 with a rotating cutter 26 (col. 1) whose distal end is not suitable for deploying a marker as taught. Thus, the plunger of Barsch is not separable into two parts since the shape of the distal end of both is critical to their function. Such a design choice is not enabled sufficiently with reference to Barsch to yield a device able to selectively cut and to deploy a marker.

The cited references fail to appreciate a problem addressed by a cutter driven pusher. Applicants point out that advantages of such an arrangement were indeed pointed out in the Specification, for example in the Summary of the Invention:

[0014] The invention overcomes the above-noted and other deficiencies of the prior art by providing a marker introducing assembly that advantageously conforms to a biopsy probe and is actuated by a cutter of a biopsy handle to deploy a biopsy marker out of a distal end of the biopsy probe. Thereby, a surgeon may advantageously position the biopsy probe to a desired surgical site and actuate a cutter control to deploy the marker while having another hand free to perform other functions such as positioning an ultrasonic transceiver for imaging the biopsy probe.

Consequently, reconsideration and allowance of claim 1, as well as claims 2-6, 8-9, and 11 that depend from, is respectfully requested.

Turning to independent claim 12, the claim recites an apparatus having an analogous limitation described above for the method claim 1 and was rejected on the same basis. Reconsideration and allowance is thus appropriate for the same reasons given above for claim 1, as well as for claims 13-19 that depend therefrom.

Turning to independent claim 20, the claim recites an apparatus having an analogous limitation described above for the method claim 1 and the Examiner relied upon the cited references to

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teach this limitation as described above. Reconsideration and allowance is thus appropriate for the same reasons given above for claim 1, as well as for claims 21-24 that depend therefrom.